

repair of lacerations and wounds, castrations, and other procedures requiring mild to moderate analgesia. Supplemental doses when required should be less than the initial dose and the total dose given should not exceed 12 milligrams per pound of body weight. The maximum total safe dose is 13.6 milligrams per pound of body weight.

(ii) In healthy cats: An initial intramuscular dosage of 4.4 to 5.4 milligrams per pound of body weight is recommended for such procedures as dentistry, treatment of abscesses, foreign body removal, and related types of surgery; 4.8 to 5.7 milligrams per pound of body weight for minor procedures requiring mild to moderate analgesia, such as repair of lacerations, castrations, and other procedures of short duration. Initial dosages of 6.5 to 7.2 milligrams per pound of body weight are recommended for ovariohysterectomy and onychectomy. When supplemental doses are required, such individual supplemental doses should be given in increments that are less than the initial dose and the total dose given (initial dose plus supplemental doses) should not exceed the maximum allowable safe dose of 32.7 milligrams per pound of body weight.

(3) *Limitations.* Discard unused reconstituted solution after 48 hours. Not for use in dogs and cats with pancreatic disease, or with severe cardiac or pulmonary dysfunction. Not for use in pregnant animals. Not for use in cats suffering with renal insufficiency. The dosage should be reduced in geriatric dogs and cats. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[47 FR 15328, Apr. 9, 1982, as amended at 51 FR 24142, July 2, 1986]

#### § 522.2471 Tilmicosin phosphate injection.

(a) *Specifications.* Each milliliter contains 300 milligrams of tilmicosin base as tilmicosin phosphate.

(b) *Sponsor.* See 000986 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.735 of this chapter.

(d) *Conditions of use*—(1) *Cattle*—(i) *Amount.* 10 milligrams per kilogram body weight.

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *P. haemolytica*.

(iii) *Limitations.* For use only in cattle as a single subcutaneous injection. Not for human use. Use of this antibiotic in humans may prove fatal. Do not use in automatically powered syringes. Do not inject more than 15 milliliters per injection site. If no improvement is noted within 48 hours, the diagnosis should be reevaluated. Do not use intravenously in cattle. Intravenous injection in cattle will be fatal. Do not use in other animal species. Injection of this antibiotic has been found to be fatal in swine and nonhuman primates, and it may be fatal in horses. Safety of use in pregnant and breeding animals has not been established. Do not use in female dairy cattle 20 months of age or older. Use of this antibiotic in this class of cattle may cause milk residues. Do not slaughter within 28 days of last treatment. Federal law restricts this drug to use or on the order of a licensed veterinarian.

(2) [Reserved]

[57 FR 12712, Apr. 13, 1992, as amended at 62 FR 5526, Feb. 6, 1997; 63 FR 7701, Feb. 17, 1998; 63 FR 14818, Mar. 27, 1998]

#### § 522.2474 Tolazoline hydrochloride injection.

(a) *Specifications.* Each milliliter of sterile aqueous solution contains tolazoline hydrochloride equivalent to 100 milligrams of base activity.

(b) *Sponsor.* See No. 061690 in § 510.600(c) of this chapter.

(c) *Conditions of use.* It is used as follows:

(1) *Horses*—(i) *Amount.* Administer slowly by intravenous injection 4 milligrams per kilogram of body weight or 1.8 milligrams per pound (4 milliliters per 100 kilograms or 4 milliliters per 220 pounds).

(ii) *Indications for use.* For use in horses when it is desirable to reverse the effects of sedation and analgesia caused by xylazine.

(iii) *Limitations.* The safety of Tolazine™ has not been established in

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pregnant mares, lactating mares, horses intended for breeding, foals, or horses with metabolically unstable conditions. The safety of Tolazine™ has not been evaluated for reversing xylazine used as a preanesthetic to a general anesthetic. This drug is for use in horses only and not for use in food-producing animals. Users with cardiovascular disease (for example, hypertension or ischemic heart disease) should take special precautions to avoid accidental exposure to this product.

Accidental spillage on the skin should be washed off immediately with soap and water. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(2) [Reserved]

[61 FR 25785, May 23, 1996]

## § 522.2476 Trenbolone acetate.

(a) [Reserved]

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(1) No. 021641 for use as in paragraphs (d)(1) and (d)(2) of this section.

(2) No. 057926 for use as in paragraphs (d)(1)(i)(A), (d)(1)(ii), (d)(1)(iii), (d)(2)(i)(A), (d)(2)(ii), and (d)(2)(iii) of this section.

(c) *Related tolerances.* See § 556.739 of this chapter.

(d) *Conditions of use—(1) Steers fed in confinement for slaughter—(i) Amount.* Use 126 days prior to slaughter; should be reimplanted once after 63 days.

(A) 140 milligrams (mg) trenbolone acetate (one implant consisting of 7 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 140 mg trenbolone acetate (one implant consisting of 8 pellets, each of 7 pellets containing 20 milligrams trenbolone acetate, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(ii) *Indications for use.* For improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

(2) *Heifers fed in confinement for slaughter—(i) Amount.* Use last 63 days prior to slaughter.

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(A) 200 mg trenbolone acetate (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate) per implant dose.

(B) 200 mg of trenbolone acetate (one implant consisting of 11 pellets, each of 10 pellets containing 20 mg of trenbolone acetate, and 1 pellet containing 29 mg of tylosin tartrate) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.

[66 FR 47961, Sept. 17, 2001]

## § 522.2477 Trenbolone acetate and estradiol.

(a) [Reserved]

(b) *Sponsors.* See sponsors in § 510.600(c) of this chapter for uses as in paragraph (d) of this section.

(1) No. 021641 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(B), (d)(1)(ii), (d)(1)(iii), and (d)(3) of this section.

(2) No. 057926 for use as in paragraphs (d)(1)(i)(A), (d)(1)(i)(C), (d)(1)(i)(D), (d)(1)(ii), (d)(1)(iii), (d)(2), (d)(3)(i)(A), (d)(3)(ii), and (d)(3)(iii) of this section.

(c) *Related tolerances.* See §§ 556.240 and 556.739 of this chapter.

(d) *Conditions of use—(1) Steers fed in confinement for slaughter—(i) Amount.*

(A) 120 milligrams (mg) trenbolone acetate and 24 mg estradiol (one implant consisting of 6 pellets, each pellet containing 20 mg trenbolone acetate and 4 mg estradiol) per implant dose.

(B) 120 mg trenbolone acetate and 24 mg estradiol (one implant consisting of 7 pellets, each of 6 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

(C) 200 mg trenbolone acetate and 20 mg estradiol (one implant consisting of 10 pellets, each pellet containing 20 mg trenbolone acetate and 2 mg estradiol) per implant dose.

(ii) *Indications for use.* For increased rate of weight gain and improved feed efficiency.

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals.